UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,626	10/30/2000	Daniel J. Sullivan	1001.1413102	7050

28075 7590 12/29/2004

CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
MARMOR II, CHARLES ALAN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/699,626	SULLIVAN, DANIEL J.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed October 6, 2004. The Examiner acknowledges the Remarks filed therewith and that no amendments are made to the claims. Claims 37-42 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al. ('465). Moore et al. teach a laser fiber (16) that is advanced through and beyond the distal end (20) of an intravascular catheter apparatus (2), and thus can be considered an intravascular guidewire. The guidewire (16) includes an elongate shaft having a radiopaque distal tip and a plurality of radiopaque sections (132) disposed on the shaft proximal of the tip that are evenly spaced axially therealong at predetermined distances from one another by a plurality of relatively non-radiopaque sections (see Fig. 8 and column 15, lines 28-45). The plurality of radiopaque markers evenly spaced axially at predetermined distances along the guidewire provide visual confirmation of the rate of movement, the distance progressed, or the relative location of the guidewire at all times. Moore et al. teach all of the limitations of the claims except for the particular width of the relatively non-radiopaque sections. The Examiner notes that Applicant has failed to state

why relatively non-radiopaque sections that are 1.5 cm wide and radiopaque sections that are 1 mm wide are critical to the present invention. It would have been an obvious design choice to one having ordinary skill in the art at the time the invention was made to use the claimed 1.5 cm distance between radiopaque markers as the predetermined distance between radiopaque markers along the intravascular guidewire of Moore et al. since these dimensions were within the ordinary spacing and size used in the art.

Furthermore, "where the only difference between the prior art and the claims (is) a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device (is) not patentably distinct from the prior art device." MPEP 52144.04 citing Gardner B. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

4. Claims 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al. ('465) in view of Tanabe et al. ('879). Moore et al., as discussed hereinabove, teach all of the limitations of the claims except that the radiopaque sections are 1 mm wide. As stated above, the Examiner notes that Applicant has failed to state why relatively non-radiopaque sections that are 1.5 cm wide and radiopaque sections that are 1 mm wide are critical to the present invention. Tanabe et al. teach an intravascular device (1) that includes a plurality of radiopaque markers (3) spaced axially therealong, where the markers are 1 mm wide (column 4, lines 18-21). It would have been an obvious design choice to one having ordinary skill in the art at the time the invention was made to use the claimed 1 mm width of radiopaque markers as the width of the

radiopaque markers along the intravascular guidewire of Moore et al. since these dimensions were within the ordinary spacing and size used in the art as evidenced by the teachings of Tanabe et al.

5. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. ('511) in view of Doyle et al. ('434), and further in view of Moore et al. ('465). Huter et al. teach a guidewire having an elongate solid shaft (12). The guidewire further comprises a proximal end (13A) and distal end (15) with a taper towards its distal end. A plurality of radiopaque markers (20, 22) is proximal of the coil tip (33) (See column 4, lines 20-26 and Fig. 1). The radiopaque markers have a width of about 0.25mm to 2.5mm, preferably 0.76mm to about 1.8mm (See column 4, lines 38-43). While disclosing a distal solder (38) at the distal end (15), Huter et al. do not specifically recite a radiopaque coil tip. Doyle et al. teach a guidewire with radiopaque markers and a radiopaque coil tip (30), typically made of solder (See column 4, 1ines 17-22). Huter et al and Doyle et al. do not teach a plurality of evenly spaced radiopaque markers nor the dimensions of the longitudinal space between the markers. As discussed above, Moore et al. teach that it is advantageous to dispose a plurality of radiopaque markers evenly spaced at predetermined distances along the guidewire so as to provide visual confirmation of the rate of movement, the distance progressed, or the relative location of the guidewire at all times. Also as discussed above, the Examiner notes that Applicant has failed to state why relatively non-radiopaque sections that are 1.5 cm wide and radiopaque sections that are 1 mm wide are critical to the present invention. It would have been an obvious design choice to one having ordinary skill in the art at the time the

invention was made to use the a plurality of evenly spaced markers at a distance of 1.5 cm separation with a guidewire similar to that of Huter et al. as modified by Doyle et al. hereinabove, in order to provide visual confirmation of the rate of movement, the distance progressed, or the relative location of the distal portion of the guidewire at all times.

Furthermore, "where the only difference between the prior art and the claims (is) a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device (is) not patentably distinct from the prior art device." MPEP 52144.04 citing Gardner B. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 39-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7 and 8 of U.S. Patent No.

5,209,730. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are merely broader than claims 7 and 8 of the patent. All of the limitations of claims 39 and 41 of the present application are recited in claim 7 of the patent. The subject matter of claims 40 and 42 of the present application corresponds to that recited in claim 8 of the patent. Since the aforementioned claims of the present application are "anticipated" by the aforementioned claims of the patent, the claims are not patentably distinct.

Response to Arguments

8. Applicant's arguments with respect to claims 37-42 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Huter et al. and Doyle et al. fail to teach markers defining a plurality of 1.5 cm longitudinal spaces therebetween. Applicant further contends that the plurality of 1.5 cm longitudinal spaces are advantageous over the prior art because it corresponds to the distance between the distal end of a balloon catheter and the midpoint of the balloon, where a marker band is placed. Applicant alleges that because of this feature the patient and staff may be subject to less radiation exposure and the patient will have fewer complications from dye injections (see page 14, lines 14-18) and that the evenly spaced markers 1.5 cm apart allows the physician to align one marker and use adjacent markers to determine precisely how much of the stenosis will be contacted by the balloon member when it is inflated (see page 14, lines 4-6). These arguments are moot in view of the new grounds of rejection citing Moore et al. set forth hereinabove.

The Examiner maintains the position that Applicant has failed to disclose why the

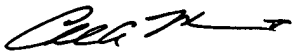
1.5 cm spacing between radiopaque markers is critical to the guidewire of the present invention. The only reference to the dimensions of the radiopaque markers and the spacing distance therebetween occur at page 4, lines 19-25 and page 8, line 28 - page 9, line 5 of the specification. These passages do not support the notion that these dimensions are critical to the present invention, since both paragraphs define "a preferred embodiment" suggesting that other dimensions are possible. Furthermore, there is no disclosure as to why a 1.5 cm longitudinal spacing is advantageous with respect to, for example, a 1.3 cm spacing or a 1.7 cm spacing between radiopaque markers. Finally, with regard to the purported advantages of these dimensions, pointed to by Applicant in the Remarks, at pages 13 and 14 of the specification, the disclosure of the application appears to suggest that these advantages would result with a predetermined, equal spacing between radiopaque markers of any dimension and not only with the claimed 1.5 cm spacing between markers. The Examiner respectfully reiterates that "where the only difference between the prior art and the claims (is) a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device (is) not patentably distinct from the prior art device." MPEP 52144.04 citing Gardner B. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
December 20, 2004